

CHARGE: 501 (d) (2)—while held for sale, sulfamethazine had been substituted for sodium sulfamethazine, which the article was represented to be; 502 (a)—the label on the boxes of the article contained false and misleading representations that the article consisted of sulfamethazine and that it was an adequate and effective treatment for retained afterbirth, congested lungs, and acute mastitis in cattle, and distemper and colds in horses.

502 (f) (2)—the labeling of the article failed to warn that the article may cause severe toxic reactions and irreparable damage if the blood levels become too high; that constant supervision of the animals was essential during treatment; and that use of the article should be discontinued if toxic symptoms appeared.

DISPOSITION: 12-1-55. Consent—claimed by Stockton Veterinary Supply Co. and relabeled.

5007. Solu-Stilbestrol. (F. D. C. No. 38980. S. No. 26-201 M.)

QUANTITY: 23 1-gal. cans at Coon Rapids, Iowa.

SHIPPED: 12-28-54 and 4-1-55, from Chicago, Ill., by Vitamins, Inc.

LABEL IN PART: (Can) "Vit Inc 1 Gal. Solu-Stilbestrol-50 Containing 50 gm. diethylstilbestrol with a solubilizing agent dissolved in 1 gal. molasses.

CAUTION: For manufacturing, processing or repackaging of the preparation of a new drug limited by federal law to investigational use. Control #15530 Manufactured by Vitamins, Inc. 809 W. 58th St. Chicago 21, Ill., U. S. A. For Manufacturing Use."

RESULTS OF INVESTIGATION: Diethylstilbestrol intended for feeding to cattle for increasing their weight is regarded as a "new drug" ingredient.

Vitamins, Inc., filed a new-drug application for the article on 6-10-55 and submitted data concerning the use made of the article by the consignee, Garst Co., Coon Rapids, Iowa. These data were verified by information obtained by Food and Drug inspectors and showed that Garst Co. mixed the diethylstilbestrol preparation with cattle feed and fed the resultant mixture to its animals for fattening purposes, and showed further that no scientific tests of any real nature were conducted in connection with the feeding. In such circumstances, the new-drug application was not made effective.

LIBELED: On or about 3-8-56, N. Dist. Iowa.

CHARGE: 502 (f) (1)—the label of the article, when shipped and while held for sale, did not bear adequate directions for use, and the article was not entitled to any exemption from that requirement since the article had not been used and was not being used only in the manufacture of a new drug limited to investigational use as provided in the regulations.

DISPOSITION: 4-24-56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5008. Various drugs. (F. D. C. No. 37994. S. Nos. 19-261/71 M.)

QUANTITY: 161 btl. of *Asmax* tablets, 151 btl. of *Lipolin*, 108 btl. of *Aratex* tablets, 6 btl. of *amino acid wafers*, 35 btl. of *Rectone* tablets, 50 btl. of *herbal diuretic tablets*, 56 14-oz. btl. and 13 8-oz. btl. of *Detoxo*, and 54 btl. of *Glutamins* tablets at Akron, Ohio.

*See also No. 5006.